

Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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Supplementary Material

Salloway S et al. Bapineuzumab Phase 3 Trial Results in Mild-to-Moderate Alzheimer's Disease

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Section 2. Inclusion and Exclusion Criteria (verbatim from the Study Protocol)

Inclusion Criteria

Subjects enrolled in this study were required to meet the following inclusion criteria:

- 50 to <89 years of age.
- Diagnosed with probable AD according to the National Institute of Neurological and Communicative Disorders and Stroke/Alzheimer's Disease and Related Disorders Association (NINCDS/ADRDA) criteria and had a screening visit brain MRI scan consistent with the diagnosis of AD.
- An MMSE score of 16 to 26 inclusive.
- Rosen Modified Hachinski Ischemic score ≤4.
- Lived at home or independently in a community dwelling; had a caregiver capable of accompanying the subject on all clinic visits, visited the subject approximately 5 times per week for the duration of the study, and was a reliable informant in the opinion of the investigator.
- Received stable doses of medication(s) for the treatment of nonexcluded medical condition(s) for at least 30 days prior to screening. Concurrent treatment with cholinesterase inhibitors and/or memantine was allowed if the subject was maintained on a stable dose regimen for at least 120 days prior to screening; was free of any clinically significant side effects attributable to the drug; and agreed (with caregiver agreement) to continue the same regimen for the duration of the trial.
- Agreed to undergo *APOE*E4* testing and agree to disclosed *APOE*E4* carrier status to the Investigator, and was a noncarrier of *APOE*E4* according to genotyping at screening.
- Subject or the subject's legally acceptable representative signed and dated written informed consent. The subject's caregiver must have consented to participate in the study.

Exclusion Criteria

Subjects were not enrolled into the study if it was determined upon prestudy examination that they:

- Had any of the following medically significant conditions:
 - Neurological disease, other than AD, that may have affected cognition; myocardial infarction within the last 2 years; uncontrolled hypertension within the last 6 months.
 - History of or screening visit brain MRI scan indicative of any other significant abnormality, including but not limited to 2 or more microhemorrhages, prior hemorrhage >1 cm³, 2 or more lacunar infarcts, prior infarct >1 cm³, cerebral contusion, encephalomalacia, aneurysms, vascular malformations, subdural hematoma, or space occupying lesions;
 - Presence of a clinically significant major psychiatric disorder (eg, major depressive disorder) according to the criteria of the Diagnostic and Statistical Manual of Mental

Disorders, Fourth Edition (DSM-IV) or symptom (eg, hallucinations) that could affect the subject's ability to complete the study;

- History of clinically evident stroke or clinically significant carotid or vertebrobasilar stenosis or plaque; seizures, excluding febrile seizures in childhood; cancer within the last 5 years, with the exception of nonmetastatic basal cell carcinoma, and squamous cell carcinoma of the skin.
- Clinically significant chronic illness which was likely to result in deterioration of the subject's condition or affect the subject's safety during the study.
- History or evidence of any clinically significant autoimmune disease or disorder of the immune system (eg, Crohn's disease, rheumatoid arthritis).
- Clinically significant infection 30 days prior to screening or the development of any clinically significant infection during Visits 1 through 3 (inclusive) (eg, chronic persistent or acute infection [eg, upper respiratory infection, urinary tract infection {UTI}]).
- Met any of the following criteria:
 - Hemoglobin <11 g/dL.
 - Substance abuse as defined by DSM-IV criteria within the last 2 years.
 - Any known hypersensitivity to any of the excipients contained in the study drug formulation.
 - Women of childbearing potential.
 - Presence of pacemakers, aneurysm clips, artificial heart valves, ear implants, CSF shunts, claustrophobia, metal fragments or foreign objects in the eyes, skin, or body that would contraindicate a brain MRI scan.
 - Other clinically significant abnormality on physical, neurological, laboratory, vital signs or ECG examination (eg, atrial fibrillation) that could compromise the study or be detrimental to the subject.
 - Discontinued cholinesterase inhibitors, memantine, or cognitive enhancing agents within 60 days prior to screening, or drugs that potentially affect cognition in the 30 days prior to screening (including but not limited to anxiolytics, sedatives, hypnotics, antipsychotics, herbal preparations, antidepressants, over-the-counter [OTC] sleeping aids, sedating anti-allergy medications, vitamin E, thyroid supplements, vitamin B12 supplements by injection).
- Were receiving any of the following treatments:
 - Treatment with immunosuppressive medications (eg, systemic corticosteroids) within the last 90 days (topical and nasal corticosteroids and inhaled corticosteroids for asthma were permitted) or chemotherapeutic agents for malignancy within the last 3 years.
 - Anticonvulsant drugs for seizures, antiparkinson drugs, anticoagulant medications (except the use of aspirin 325 mg/day or less, Plavix®, and Persantine® but not for stroke), opioid pain relievers, or related synthetic derivatives.

- Prescription or nonprescription medication for cognitive enhancement other than cholinesterase inhibitors and memantine as previously described.
 - Any other medications with the potential to affect cognition other than cholinesterase inhibitors or memantine, unless maintained on a stable dose regimen for at least 30 days prior to screening.
 - Experimental medications for AD or any other investigational medications or devices for treatment of indications other than AD within 60 days prior to screening or within 5 half-lives of use of such a medication prior to screening, whichever was longer.
- Were involved in any of the following investigational procedures:
 - Any prior experimental treatment with AN1792, bapineuzumab, ACC-001, or other experimental immunotherapeutic or vaccine for AD.
 - Any prior treatment with a biological product other than for the treatment of AD within the last 3 years with the exception of yearly routine vaccines that were commercially available.

Section 3. Description of Study Populations and Statistical Models

Study Procedures

Include intervals of infusions and testing, primary outcomes and biomarkers. Site personnel remained blinded to the treatment dose or placebo except the unblinded pharmacist who prepared the medication.

Description of Primary Endpoints (verbatim from the Statistical Analysis Plan)

The Alzheimer's Disease Assessment Scale – Cognitive subscale (ADAS-Cog) is a global cognitive measure that has been used in AD treatment trials to demonstrate efficacy in symptomatic cognitive improvement. The ADAS-Cog/11 is an 11-item, objective measure of cognitive function. The scale evaluates memory, language, and praxis with items such as orientation, word recall, word recognition, object identification, comprehension, and the completion of simple tasks. Scores range from 0 to 70 points, with higher scores indicating a greater degree of impairment.

The Disability Assessment for Dementia (DAD) measures instrumental and basic activities of daily living in AD subjects. The DAD is administered to the subject's caregiver in the form of an interview. This scale assesses a subject's ability to initiate, plan and perform activities related to hygiene, dressing, continence, eating, meal preparation, telephoning, going on an outing, finance, and correspondence, medications, leisure, and housework.

Description of Individual Study Populations (verbatim from the Statistical Analysis Plan)

The Modified Intent-to-Treat (mITT) Analysis Population is defined as all randomized subjects who received at least 1 infusion or portion of an infusion of study drug and who had a baseline and at least 1 postbaseline assessment of the ADAS-Cog/11 total score and DAD total score.

The PiB PET Analysis Population includes all randomized subjects who enrolled in the PET substudy and who met the following criteria: a) received at least 1 infusion or portion of an infusion of study drug, b) had a baseline and at least 1 postbaseline ¹¹C-PiB PET assessment, and c) had an SUV_r for the GCA ROI ≥ 1.35 at baseline. The GCA SUV_r is the average of the SUV_r values for the following 5 cortical ROIs: anterior cingulate, posterior cingulate/precuneus, frontal cortex, lateral temporal cortex, and parietal cortex. The SUV_r is equivalent to the ratio of target region radioactivity to reference region radioactivity. The cerebellar gray matter is being used in the PET substudy as the reference region. Given that the primary hypothesis of the PiB PET investigation is that bapineuzumab treatment will reduce brain amyloid burden, only subjects with adequate brain amyloid at baseline for this assessment will be included in the primary analysis population for the substudy. The threshold of ≥ 1.35 was determined based on the inclusion/exclusion criteria in the completed Phase 2 PET Study AAB-001-202 and refined by subsequent reports of lower SUV_r values in *APOE*E4* noncarriers with AD than carriers.

The CSF Analysis Population includes all randomized subjects who enrolled in the CSF substudy, received at least 1 infusion or portion of an infusion of study drug, and had a baseline and at least 1 postbaseline CSF measurement collected on or after Week 52 (Day 365).

The vMRI Analysis Population includes all randomized subjects who enrolled in the vMRI substudy, received at least 1 infusion or portion of an infusion of study drug, and had a baseline and at least 1 postbaseline vMRI that passed quality control (QC) and was satisfactory for volumetric analysis.

Description of Individual Study Analyses (verbatim from the Statistical Analysis Plan)

For each coprimary endpoint, the Hochberg approach will be used to control for testing the 2 dose levels (0.5 mg/kg and 1.0 mg/kg) of bapineuzumab. A dose will be considered effective only if the p-value for both coprimary outcomes satisfies Hochberg criteria for statistical significance. Because both must be significant, no further correction for multiplicity is required for the coprimary endpoints.

PiB PET: Change in ¹¹C-PiB PET GCA SUV_r from baseline to Week 71 was analyzed using a similar MMRM as described for the primary clinical endpoints, with the relevant baseline covariates. The pooled analysis of the 0.5-mg/kg and 1.0-mg/kg dose in the non-carrier study was considered the primary analysis. A negative change from baseline indicates a reduction in fibrillar amyloid burden. Treatment differences (bapineuzumab - placebo) were estimated using least-squares (LS) means with factor levels weighted according to overall baseline sample proportions; a negative treatment difference indicates a reduction in fibrillar amyloid burden with bapineuzumab compared to placebo.

P-tau: Change in CSF p-tau from baseline to Week 71 was analyzed using an analysis of covariance (ANCOVA) model with terms for treatment, baseline, baseline MMSE stratum, baseline cholinesterase inhibitor or memantine use, *APOE** $\epsilon 4$ copy number (in carriers), and baseline age. The pooled analysis of the 0.5-mg/kg and 1.0-mg/kg dose in the non-carrier study was considered the primary analysis.

Volumetric MRI: The Brain Boundary Shift Integral (BBSI) was analyzed based on the treatment differences estimated at Week 71 using a similar MMRM as described for the primary analyses but with baseline whole brain volume (WBV) used as a covariate in the model. Treatment differences (bapineuzumab - placebo) are estimated using least-squares (LS) means with factor levels weighted according to overall baseline sample proportions; a negative difference represents less brain shrinkage for bapineuzumab compared to placebo.

Subgroup analyses by baseline disease severity, defined using baseline MMSE total score, will be performed. The mild AD subgroup consists of subjects with baseline MMSE total score ≥ 21 and the moderate AD subgroup consists of subjects with baseline MMSE total score ≤ 20 . Additional exploratory analyses to examine the sensitivity of the MMSE cutpoint will be performed using alternative definitions of “mild” and “moderate” AD (such as MMSE total score ≥ 20 [mild] versus MMSE total score ≤ 19 [moderate] or MMSE total score ≥ 22 [mild] versus MMSE total score ≤ 21 [moderate]).

Section 4. Listing of Pre-specified Efficacy and Biomarker Analyses by Variable (verbatim from the Statistical Analysis Plan)

The sections are organized with the endpoint definition provided first, followed by the analyses that will be performed on that endpoint. The endpoints are presented in order of importance: co-primary, key secondary, secondary, and exploratory. The subgroup analyses in mild AD subjects are considered important, as these will provide a supporting piece of a prospectively planned meta-analysis in the mild AD population and as such, have been placed in their own section. The details of the meta-analysis will be described in a separate statistical analysis plan.

Variable	Analysis	Endpoint	Included in Manuscript
ADAS-Cog/11	Change from baseline in total score at Week 78 (MMRM)	Coprimary	Yes
	Change from baseline in total score at all other time points (MMRM)	Other	No
	Assessment of dropout pattern and efficacy profile by early termination reasons	Other	No
	Assessment of robustness of primary analysis model	Other	No
	Change from baseline in total score at Week 78 using multiple imputation method	Other	No
	Change from baseline in total score at Week 78 (Retrieved Dropout Analysis)	Other	No
	Change from baseline in total score over time by time on AD background therapy (descriptive statistics)	Other	No
	Change from baseline in total score over time by baseline use of cholinesterase inhibitors and memantine (descriptive statistics)	Other	No
	Time to first clinically meaningful deterioration (log-rank test)	Key Secondary	No
	Divergence of effect from Week 26 to Week 78	Other	No
	Divergence of effect from Week 39 to Week 78 using the multiple imputation datasets	Other	No
	Analyses of primary, key secondary, and secondary endpoints by mild/moderate AD subgroups	Other Secondary	Yes - Supplementary
	Responder analysis at Week 78 (Cochran-Mantel-Haenszel test)	Secondary	No
	Responder analysis at Weeks 52 and 65 (Cochran-Mantel-Haenszel test)	Other	No
	Cumulative response curves at Week 78	Secondary	No
DAD	Cumulative response curves at Weeks 52 and 65	Other	No
	Spearman and Pearson correlations between change in total score and the following biomarkers: ¹¹ C-PiB PET GCA SUVR, CSF p-tau, vMRI BBSI	Other	No
	MANOVA approach to evaluate the relationship between change in total score and the following biomarkers: ¹¹ C-PiB PET GCA SUVR, vMRI BBSI	Other	No
	ANCOVA approach to evaluate the relationship between change in total score and CSF p-tau	Other	No
	Change from baseline in total score over time by baseline cholinesterase inhibitor or memantine use stratum (descriptive statistics)	Other	No
	Change from baseline in total score at Week 78 (MMRM)	Coprimary	Yes

Variable	Analysis	Endpoint	Included in Manuscript
	Change from baseline in total score at all other time points (MMRM)	Other	No
	Assessment of dropout pattern and efficacy profile by early termination reasons	Other	No
	Assessment of robustness of primary analysis model	Other	No
	Change from baseline in total score at Week 78 using multiple imputation method	Other	No
	Change from baseline in total score at Week 78 (Retrieved Dropout Analysis)	Other	No
	Change from baseline in total score over time by time on AD background therapy (descriptive statistics)	Other	No
	Change from baseline in total score over time by baseline use of cholinesterase inhibitors and memantine (descriptive statistics)	Other	No
	Time to first clinically meaningful deterioration (log-rank test)	Key Secondary	No
	Divergence of effect from Week 39 to Week 78	Key Secondary	No
	Divergence of effect from Week 26 to Week 78	Other	No
	Divergence of effect from Week 39 to Week 78 using the multiple imputation datasets	Other	No
	Analyses of primary, key secondary, and secondary endpoints by mild/moderate AD subgroups	Other Secondary	Yes-Supplementary
	Responder analysis at Week 78 (Cochran-Mantel-Haenszel test)	Secondary	No
	Responder analysis at Weeks 52 and 65 (Cochran-Mantel-Haenszel test)	Other	No
	Cumulative response curves at Week 78	Secondary	No
	Cumulative response curves at Weeks 52 and 65	Other	No
	Spearman and Pearson correlations between change in total score and the following biomarkers: 11C-PiB PET GCA SUVR, CSF p-tau, vMRI BBSI	Other	No
	MANOVA approach to evaluate the relationship between change in total score and the following biomarkers: 11C-PiB PET GCA SUVR, vMRI BBSI	Other	No
	ANCOVA approach to evaluate the relationship between change in total score and CSF p-tau	Other	No
	Change from baseline in total score over time by baseline cholinesterase inhibitor or memantine use stratum (descriptive statistics)	Other	No

Variable	Analysis	Endpoint	Included in Manuscript
DS	Change from baseline in total score at Week 78 (MMRM)	Key Secondary	Yes
	Change from baseline in total score at all other time points (MMRM)	Other	No
	Equivalent Institutional Care at all time points (descriptive statistics)	Other	No
	Responder analysis at Week 78 (Cochran-Mantel-Haenszel test)	Other	No
	Analyses of key secondary and secondary endpoints by mild/moderate AD subgroups	Other Secondary	No
11C-PiB PET	Change from baseline in GCA SUVR at Week 71 using the pooled bapineuzumab dose group (MMRM)	Key Secondary	Yes
	Change from baseline in GCA SUVR at Week 71 using individual bapineuzumab dose groups (MMRM)	Other	Yes
	Change from baseline in GCA SUVR at all other time points using the pooled bapineuzumab dose group (MMRM)	Other	No
	Change from baseline in GCA SUVR at all other time points using individual bapineuzumab dose groups (MMRM)	Other	No
	Change from baseline in the individual ROIs at all time points (MMRM)	Other	No
	Spearman and Pearson correlations between change in GCA SUVR and ADAS-Cog/11 and DAD total scores	Other	No
	MANOVA approach to evaluate the relationship between change GCA SUVR and ADAS-Cog/11 and DAD total scores	Other	No
	Analyses of key secondary and secondary endpoints by mild/moderate AD subgroups	Other Secondary	No
	Change from baseline in p-tau at Week 71 using the pooled bapineuzumab dose group (ANCOVA)	Key Secondary	Yes
CSF p-tau	Change from baseline in p-tau at Week 71 using individual bapineuzumab dose groups (ANCOVA)	Other	Yes
	Spearman and Pearson correlations between change in p-tau and ADAS-Cog/11 and DAD total scores	Other	No
	ANCOVA approach to evaluate the relationship between change in p-tau and ADAS-Cog/11 and DAD total scores	Other	No
	Analyses of key secondary and secondary endpoints by mild/moderate AD subgroups	Other Secondary	No
	Change from baseline in t-tau at Week 71 (ANCOVA)	Other	No
CSF Aβ	Change from baseline in A β at Week 71 (ANCOVA)	Other	No
vMRI BBSI	BBSI at Week 71 (MMRM)	Key Secondary	Yes
	BBSI at all other time points (MMRM)	Other	No

Variable	Analysis	Endpoint	Included in Manuscript
	Spearman and Pearson correlations between BBSI and ADAS-Cog/11 and DAD total scores	Other	No
	MANOVA approach to evaluate the relationship between BBSI and ADAS-Cog/11 and DAD total scores	Other	No
vMRI BBSI	Analyses of key secondary and secondary endpoints by mild/moderate AD subgroups	Other Secondary	No
vMRI VBSI	VBSI at all time points (MMRM)	Other	No
vMRI HBSIs	HBSIs (right and left) at all time points (MMRM)	Other	No
vMRI WBV	Change from baseline in WBV at all time points (MMRM)	Other	No
vMRI VV	Change from baseline in VV at all time points (MMRM)	Other	No
vMRI HCVs	Change from baseline in HCVs (right and left) at all time points (MMRM)	Other	No
CDR-SB	Change from baseline in total score at Week 78 (MMRM)	Secondary	Yes
	Change from baseline in total score at all other time points (MMRM)	Other	No
	Cumulative response curves at Weeks 52 and 78	Other	No
	Analyses of key secondary and secondary endpoints by mild/moderate AD subgroups	Other Secondary	No
	Divergence of effect from Week 26 to Week 78	Other	No
NTB	Change from baseline in total z-score at all time points (MMRM)	Other	Yes
	Change from baseline in Immediate Memory z-score at all time points (MMRM)	Other	No
	Change from baseline in Delayed Memory z-score at all time points (MMRM)	Other	No
	Change from baseline in All Memory z-score at all time points (MMRM)	Other	No
	Change from baseline in Executive Function z-score at all time points (MMRM)	Other	No
MMSE	Change from baseline in total score at all time points (MMRM)	Other	Yes
	Divergence of effect from Week 32 to Week 78	Other	No
NPI	Change from baseline in total score at all time points (MMRM)	Other	No
	Change from baseline in caregiver distress total score at all time points (descriptive statistics)	Other	No

Abbreviations: ADAS-Cog/11 denotes Alzheimer's Disease Assessment Scale—Cognitive Subscale, 11-item (range 0 to 70; higher scores = greater impairment); DAD—Disability Assessment for Dementia (range 0 to 100; higher scores = less impairment), DS—Dependence Scale (range 0 to 15, higher scores = greater impairment); BBSI—Brain

Boundary Shift Integral; VBSI-Volume Boundary Shift Integral; WBV-Whole Brain Volume; VV-Ventricular Volume; HBSI- Hippocampal Boundary Shift Integral; HCV-Hippocampal Volume; CDR-SB-Clinical Dementia Rating Scale Sum of Boxes (range 0 to 18, higher scores = greater impairment); NTB-Neuropsychological Test Battery (standardized z-scale, higher scores = less impairment); MMSE-Mini-Mental State Exam (range 0-30, higher scores = less impairment); NPI-Neuropsychiatric Inventory (total score range 0 to 144, higher scores = greater impairment); MMRM-mixed model for repeated measures; ANCOVA-analysis of covariance; MANOVA-multivariate analysis of variance.

Supplementary Figures

Figure S1. Subject disposition for 302 (*APOE**ε4 carrier) and 301 (*APOE**ε4 non-carrier) studies

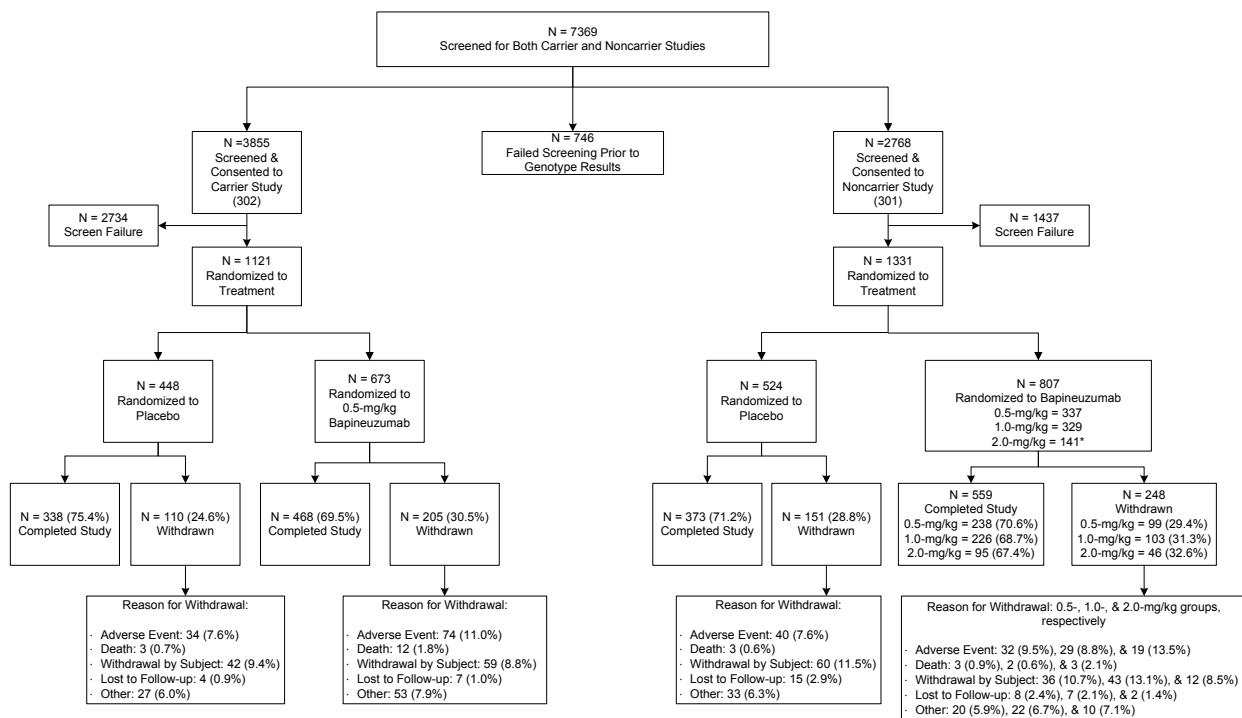
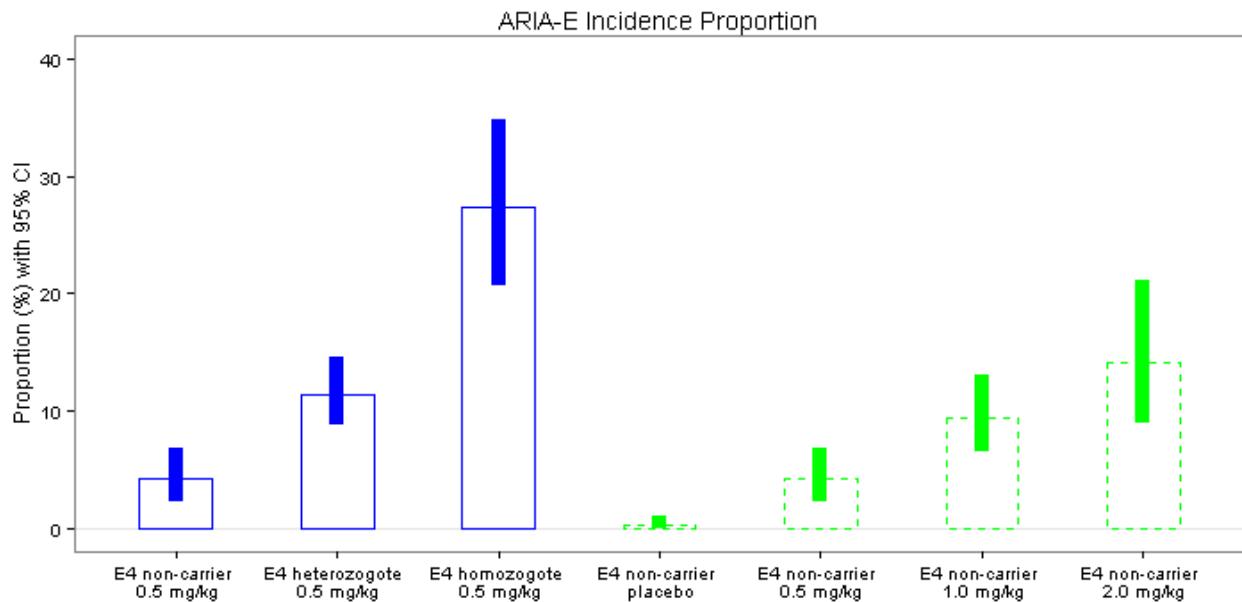


Figure S2. Rates of ARIA-E by number of *APOE** ϵ 4 alleles (at 0.5-mg/kg dose in carriers and non-carriers) and by bapineuzumab dose in non-carriers (data from the centrally read Safety MRIs)



Error bars represent the 95% exact binomial confidence interval. Statistically significant trends were found in ARIA-E incidence proportion by *APOE** ϵ 4 allele (2-sided p<0.0001) and by dose level (2-sided p<0.0001). Analyses performed using the Cochran-Armitage trend test.

Supplementary Tables

Table S1. Patient demographics and baseline characteristics (safety population)

	APOE*ε4 Carriers Total Randomized N=1121		APOE*ε4 Non-Carriers Total Randomized N=1331			
	Placebo (N=448)	Bapineuzumab 0.5-mg/kg (N=673)	Placebo (N=524)	Bapineuzumab 0.5-mg/kg (N=337)	Bapineuzumab 1.0-mg/kg (N=329)	Bapineuzumab 2.0-mg/kg (N=141)
Age, y; mean (SD)	72.4 (8.3)	72.1 (8.1)	71.8 (10.1)	73.0 (9.5)	73.2 (9.4)	73.7 (9.5)
Gender (% female)	252 (56.3)	369 (54.8)	266 (50.8)	175 (51.9)	186 (56.5)	78 (55.3)
Race (% Caucasian)	431 (96.2)	637 (94.7)	492 (93.9)	314 (93.2)	307 (93.3)	132 (93.6)
APOE*ε4: % heterozygote ε4 % homozygote ε4	337 (75.2) 111 (24.8)	508 (75.5) 165 (24.5)	--	--	--	--
AChEI or memantine use, (%)	413 (92.2)	619 (92.0)	463 (88.4)	297 (88.1)	290 (88.1)	129 (91.5)
MMSE total score; mean (SD)	20.7 (3.2)	20.7 (3.1)	21.3 (3.2)	21.2 (3.4)	21.2 (3.3)	21.0 (3.1)
ADAS-Cog/11 total score; mean (SD)	23.9 (9.8)	23.6 (9.5)	22.1 (10.1)	22.3 (9.6)	22.3 (9.9)	22.6 (8.6)
DAD total score; mean (SD)	79.1 (19.1)	80.5 (17.7)	80.5 (19.1)	80.1 (18.1)	80.4 (19.2)	77.6 (20.0)
Total infusions received (%)						
1	22 (4.9)	42 (6.2)	37 (7.1)	23 (6.8)	21 (6.4)	17 (12.1)
2	32 (7.1)	42 (6.2)	47 (9.0)	13 (3.9)	25 (7.6)	5 (3.5)
3	17 (3.8)	37 (5.5)	26 (5.0)	23 (6.8)	23 (7.0)	7 (5.0)
4	17 (3.8)	48 (7.1)	19 (3.6)	26 (7.7)	19 (5.8)	9 (6.4)
5	31 (6.9)	82 (12.2)	28 (5.3)	25 (7.4)	38 (11.6)	16 (11.3)
6	329 (73.4)	422 (62.7)	367 (70.0)	227 (67.4)	203 (61.7)	87 (61.7)
Completers	338	468	373	238	226	95

Abbreviations: APO denotes apolipoprotein, AChEI acetylcholinesterase inhibitor, MMSE Mini-Mental State Exam (range 0-30, higher scores = less impairment), ADAS-Cog/11 Alzheimer's Disease Assessment Scale – Cognitive Subscale 11-item (range 0-70, higher scores = greater impairment), DAD Disability Assessment for Dementia (range 0-100, higher scores = less impairment), SD standard deviation.

Table S2

a. Change from baseline to Week 78 for mITT subjects: Co-primary endpoints by baseline MMSE score in carriers

	Placebo LS Mean (SE)	Bapineuzumab 0.5-mg/kg LS Mean (SE)	Difference of LS Means (95% CI)	p-value
Mild Subjects Carriers (254, 339) MMSE ≥20				
ADAS-Cog/11 Total Score	6.2 (0.58)	5.9 (0.48)	-0.3 (-1.8, 1.2)	0.688
DAD Total Score	-11.5 (1.22)	-12.8 (1.00)	-1.3 (-4.4, 1.8)	0.404
Moderate Subjects Carriers (178, 259) MMSE <20				
ADAS-Cog/11 Total Score	12.3 (0.79)	12.7 (0.67)	0.4 (-1.6, 2.4)	0.706
DAD Total Score	-22.9 (1.65)	-24.3 (1.42)	-1.4 (-5.7, 2.9)	0.523
Mild Subjects Carriers (215, 339) MMSE ≥21				
ADAS-Cog/11 Total Score	5.8 (0.63)	5.2 (0.51)	-0.5 (-2.1, 1.1)	0.516
DAD Total Score	-11.1 (1.28)	-11.6 (1.04)	-0.5 (-3.7, 2.8)	0.770
Moderate Subjects Carriers (217, 319) MMSE <21				
ADAS-Cog/11 Total Score	11.7 (0.70)	12.0 (0.59)	0.4 (-1.4, 2.1)	0.701
DAD Total Score	-21.3 (1.51)	-23.5 (1.29)	-2.2 (-6.1, 1.7)	0.267
Mild Subjects Carriers (181, 278) MMSE ≥22				
ADAS-Cog/11 Total Score	5.3 (0.68)	4.9 (0.56)	-0.4 (-2.1, 1.4)	0.676
DAD Total Score	-10.1 (1.35)	-10.7 (1.12)	-0.6 (-4.0, 2.9)	0.734
Moderate Subjects Carriers (251, 380) MMSE <22				
ADAS-Cog/11 Total Score	11.2 (0.65)	11.2 (0.54)	0.0 (-1.6, 1.7)	0.967
DAD Total Score	-20.6 (1.40)	-22.3 (1.17)	-1.7 (-5.3, 1.9)	0.346

Abbreviations: MMSE Mini-Mental State Exam (range 0-30, higher scores = less impairment), ADAS-Cog/11 Alzheimer's Disease Assessment Scale – Cognitive Subscale 11-item (range 0-70, higher scores = greater impairment and higher change scores = greater impairment), DAD Disability Assessment for Dementia (range 0-100, higher scores = less impairment and higher change scores (less negative) = less impairment), SE standard error.

b. Change from baseline to Week 78 for mITT subjects : Co-primary endpoints by baseline MMSE score in non-carriers

	Placebo	Bapineuzumab			Bapineuzumab		
		0.5-mg/kg		1.0-mg/kg			
	LS Mean (SE)	LS Mean (SE)	Difference of LS Means (95% CI)	p-value	LS Mean (SE)	Difference of LS Means (95% CI)	p-value
Mild Subjects Non-carriers (334, 204, 201) MMSE ≥20							
ADAS-Cog/11 Total Score	5.2 (0.51)	4.1 (0.66)	-1.1 (-2.7, 0.5)	0.188	4.7 (0.66)	-0.5 (-2.2, 1.1)	0.513
DAD Total Score	-12.5 (1.06)	-8.9 (1.38)	3.6 (0.1, 7.0)	0.042	-8.4 (1.38)	4.1 (0.7, 7.5)	0.018
Moderate Subjects Non-carriers (159, 110, 106) MMSE <20							
ADAS-Cog/11 Total Score	12.1 (0.95)	12.5 (1.09)	0.4 (-2.5, 3.2)	0.798	13.8 (1.19)	1.7 (-1.3, 4.7)	0.265
DAD Total Score	-22.1 (1.95)	-19.5 (2.24)	2.5 (-3.3, 8.4)	0.391	-27.3 (2.44)	-5.2 (-11.4, 0.9)	0.095
Mild Subjects Non-carriers (282, 182, 176) MMSE ≥21							
ADAS-Cog/11 Total Score	4.5 (0.54)	3.8 (0.68)	-0.7 (-2.4, 1.0)	0.433	4.2 (0.68)	-0.2 (-1.9, 1.5)	0.803
DAD Total Score	-9.9 (1.07)	-8.1 (1.36)	1.8 (-1.6, 5.2)	0.297	-7.1 (1.37)	2.8 (-0.7, 6.2)	0.113
Moderate Subjects Non-carriers (211, 132, 131) MMSE <21							
ADAS-Cog/11 Total Score	11.5 (0.82)	11.5 (0.99)	-0.0 (-2.5, 2.5)	0.999	12.6 (1.04)	1.1 (-1.5, 3.7)	0.415
DAD Total Score	-23.6 (1.71)	-19.0 (2.07)	4.5 (-0.7, 9.8)	0.091	-25.0 (2.18)	-1.4 (-6.8, 4.1)	0.620
Mild Subjects Non-carriers (237, 156, 154) MMSE ≥22							
ADAS-Cog/11 Total Score	3.9 (0.57)	3.9 (0.71)	3.9 (0.71)	0.987	4.1 (0.71)	0.1 (-1.6, 1.9)	0.870
DAD Total Score	-8.1 (1.10)	-8.1 (1.38)	-0.0 (-3.5, 3.5)	0.998	-6.7 (1.39)	1.4 (-2.1, 4.9)	0.435
Moderate Subjects Non-carriers (256, 158, 153) MMSE <22							
ADAS-Cog/11 Total Score	10.8 (0.74)	10.3 (0.92)	-0.6 (-2.9, 1.8)	0.640	11.5 (0.96)	0.7 (-1.7, 3.1)	0.561
DAD Total Score	-23.1 (1.54)	-17.3 (1.91)	5.7 (0.9, 10.5)	0.020	-22.6 (1.99)	0.5 (-4.5, 5.4)	0.848

* In these pre-specified exploratory analyses, treatment differences ($p<0.05$) were observed on the DAD in mild subjects with MMSE ≥ 20 at both the 0.5-mg/kg and 1.0-mg/kg doses and in moderate subjects with MMSE <22 at 0.5 mg/kg

Abbreviations: MMSE Mini-Mental State Exam (range 0-30, higher scores = less impairment), ADAS-Cog/11 Alzheimer's Disease Assessment Scale – Cognitive Subscale 11-item (range 0-70, higher scores = greater impairment and higher change scores = greater impairment), DAD Disability Assessment for Dementia (range 0-100, higher scores = less impairment and higher change scores (less negative) = less impairment), SE standard error.

Table S3. Results for Key Biomarker Endpoints

a. *APOE*ε4* Carriers, Study 302

	Placebo	Bapineuzumab 0.5-mg/kg
PiB PET GCA SUVR		
Baseline:		
N ^a	40	75
Mean (SD)	2.105 (0.3348)	2.156 (0.3342)
Week 71:		
Mean (SD)	2.217 (0.4033)	2.165 (0.3246)
Change from baseline to Week 71: MMRM Analysis		
LS Mean (SE)	0.102 (0.0264)	0.001 (0.0207)
Difference in LS Means (95% CI)	-0.101 (-0.168, -0.034)	
p-value	0.004	
CSF p-tau		
Baseline		
N ^a	85	127
Mean (SD)	119.95 (50.698)	108.95 (38.678)
Week 71:		
Mean (SD)	121.13 (54.902)	103.43 (37.321)
Change from baseline to Week 71: ANCOVA Analysis		
LS Mean (SE), pg/mL	0.95 (1.828)	-5.80 (1.492)
Difference in LS Means (95% CI), pg/mL	-6.75 (-11.45, -2.06)	
p-value	0.005	
vMRI BBSI		
Shift from Baseline to Week 71:		
N ^a	238	352
Mean (SD)	18.4 (9.080)	19.7 (9.484)
Change from baseline to Week 71: MMRM Analysis		
LS Mean (SE), mL/year	18.7 (0.586)	19.9 (0.500)
Difference in LS Means (95% CI), mL/year	1.175 (-0.340, 2.689)	
p-value	0.128	

a. Total number of subjects in the individual analysis population

Abbreviations: GCA Global Cortical Average, SUVR Standardized Uptake Value Ratio, BBSI Brain Boundary Shift Integral, MMRM=mixed model for repeated measures, ANCOVA=analysis of covariance

b. *APOE** ϵ 4 Non-Carriers, Study 301

	Placebo	Bapineuzumab			Combined doses	
		0.5-mg/kg	1.0-mg/kg	0.5 and 1.0-mg/kg		
PiB PET GCA SUVR						
Baseline:						
N ^a	15	12	12	24		
Mean (SD)	2.085 (0.3990)	2.158 (0.3979)	1.904 (0.3925)	2.031 (0.4076)		
Week 71:						
Mean (SD)	2.018 (0.4306)	2.187 (0.4110)	1.907 (0.3297)	2.054 (0.3917)		
Change From Baseline to Week 71:						
MMRM Analysis						
LS Mean (SE) ^b	-0.046 (0.0443)	0.039 (0.0452)	-0.094 (0.0471)	-0.025 (0.0337)		
Difference of LS Means (95% CI) ^c		0.085 (-0.046, 0.215)	-0.048 (-0.182, 0.086)	0.021 (-0.099, 0.140)		
p-value		0.193	0.466	0.724		
CSF p-tau						
Baseline:						
N ^a	77	47	54	101		
Mean (SD)	104.17 (47.809)	88.54 (44.599)	105.33 (54.482)	97.51 (50.587)		
Week 71:						
Mean (SD)	101.33 (47.416)	89.27 (39.819)	98.37 (50.341)	94.06 (45.651)		
Change From Baseline to Week 71:						
ANCOVA Analysis						
LS Mean (SE) ^b	-1.98 (1.478)	-1.93 (1.911)	-8.17 (1.803)	-5.23 (1.330)		
Difference of LS Means (95% CI) ^c		0.05 (-4.78, 4.88)	-6.19 (-10.82, -1.56)	-3.30 (-7.30, 0.71)		
p-value		0.984	0.009	0.106		
vMRI BBSI						
Shift from Baseline to Week 71:						
N ^a	244	169	146	315		
Mean (SD)	17.5 (10.93)	16.2 (9.55)	18.4 (8.72)	17.2 (9.22)		
Shift From Baseline to Week 71:						
MMRM Analysis						
LS Mean (SE) ^b	17.5 (0.61)	17.2 (0.73)	19.0 (0.79)	18.0 (0.54)		
Difference of LS Means (95% CI) ^c		-0.336 (-2.216, 1.543)	1.514 (-0.459, 3.487)	0.516 (-1.093, 2.126)		
p-value		0.725	0.132	0.529		

- a. Total number of subjects in the individual analysis population
- b. LS mean (SE) values for placebo are estimated from models using the individual treatment groups (placebo, bapineuzumab 0.5-mg/kg, and bapineuzumab 1.0-mg/kg).
- c. Treatment differences reported for analyses comparing the combined doses vs. placebo are from models using placebo and the pooled bapineuzumab 0.5-mg/kg and 1.0-mg/kg doses as the treatment groups. Placebo values for models using the pooled bapineuzumab group (not reported in the table) may differ from placebo values estimated from models using the individual dose groups.

Abbreviations: GCA Global Cortical Average, SUVR Standardized Uptake Value Ratio, BBSI Brain Boundary Shift Integral, MMRM=mixed model for repeated measures, ANCOVA=analysis of covariance.

Table S4. Treatment-Emergent Adverse Events Occurring in $\geq 5\%$ of Subjects in Any Treatment Group and Occurring More Frequently with Bapineuzumab Treatment Than Placebo Treatment

a. *APOE*ε4* Carrier Study (Safety Population)

Adverse Event	Placebo N=448 n(%)	Bapineuzumab 0.5-mg/kg N=673 n(%)
Amyloid Related Imaging Abnormalities (ARIA-E, previously referred to as Vasogenic Edema)	1 (0.2)	103 (15.3)
Fall	64 (14.3)	100 (14.9)
Headache	48 (10.7)	78 (11.6)
Depression	38 (8.5)	60 (8.9)
Agitation	35 (7.8)	57 (8.5)
Diarrhea	31 (6.9)	54 (8.0)
Dizziness	31 (6.9)	54 (8.0)
Upper Respiratory Tract Infection	28 (6.3)	51 (7.6)
Confusional State	19 (4.2)	50 (7.4)
Nasopharyngitis	26 (5.8)	45 (6.7)
Nausea	26 (5.8)	44 (6.5)
Contusion	19 (4.2)	40 (5.9)
Back Pain	17 (3.8)	38 (5.6)

b. *APOE*ε4* Non-Carrier Study (Safety Population)

Adverse Event Term	Placebo N=524 n(%)	Bapineuzumab 0.5-mg/kg N=337 n(%)	Bapineuzumab 1.0-mg/kg N=329 n(%)	Bapineuzumab 2.0-mg/kg N=141 n(%)
ARIA-E (Vasogenic Edema)	1 (0.2)	14 (4.2)	31 (9.4)	20 (14.2)
Fall	73 (13.9)	43 (12.8)	43 (13.1)	23 (16.3)
Urinary Tract Infection	59 (11.3)	40 (11.9)	42 (12.8)	15 (10.6)
Anxiety	43 (8.2)	19 (5.6)	39 (11.9)	11 (7.8)
Headache	49 (9.4)	30 (8.9)	34 (10.3)	16 (11.3)
Agitation	37 (7.1)	26 (7.7)	15 (4.6)	16 (11.3)
Diarrhea	32 (6.1)	23 (6.8)	27 (8.2)	10 (7.1)
Insomnia	20 (3.8)	13 (3.9)	20 (6.1)	11 (7.8)
Nausea	25 (4.8)	14 (4.2)	11 (3.3)	10 (7.1)
Syncope	13 (2.5)	10 (3.0)	12 (3.6)	9 (6.4)
Vomiting	20 (3.8)	11 (3.3)	16 (4.9)	9 (6.4)
Confusional State	20 (3.8)	16 (4.7)	14 (4.3)	8 (5.7)
Arthralgia	23 (4.4)	11 (3.3)	17 (5.2)	8 (5.7)
Constipation	15 (2.9)	14 (4.2)	12 (3.6)	8 (5.7)
Weight Decreased	22 (4.2)	19 (5.6)	18 (5.5)	5 (3.5)
Cough	26 (5.0)	19 (5.6)	13 (4.0)	6 (4.3)

Table S5. ARIA-E Rates by Bapineuzumab Dose and *APOE** ϵ 4 Allele Status in the Retrospective Central Read Analysis.

	Placebo	Bapineuzumab 0.5-mg/kg (all subjects)	Bapineuzumab 0.5-mg/kg (1 ϵ 4 allele)	Bapineuzumab 0.5-mg/kg (2 ϵ 4 alleles)	Bapineuzumab 1.0-mg/kg	Bapineuzumab 2.0-mg/kg
<i>APOE</i> * ϵ 4 Carriers N (%)	5 (1.1)	143 (21.2)	86 (16.9)	57 (34.5)	N/A	N/A
<i>APOE</i> * ϵ 4 Non-Carriers N (%)	3 (0.6)	19 (5.6)	N/A	N/A	44 (13.4)	28 (19.9)

Separate from the Amyloid Related Imaging Abnormalities with Effusion/Edema (ARIA-E) (i.e. sulcal or parenchymal hyperintensities) reported prospectively during the course of the carrier and non-carrier studies, a retrospective central read analysis was also conducted. This analysis involved a review of all the subjects' MRI scans after the subject completed the study. This central review was performed by a team of trained neuroradiologists separate from those who were involved in the local or central reading of the MRIs ongoing during the course of the study.

Table S6. Treatment-Emergent Serious Adverse Events by System Organ Class

a. *APOE*ε4* Carrier Study (Safety Population)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Number of Subjects With Any Serious TEAE	89 (19.9)	176 (26.2)
Nervous system disorders		
Vasogenic cerebral oedema	0 (0.0)	14 (2.1)
Syncope	10 (2.2)	11 (1.6)
Convulsion	0 (0.0)	6 (0.9)
Dementia Alzheimer's type	2 (0.4)	3 (0.4)
Transient ischaemic attack	1 (0.2)	3 (0.4)
Cerebral microhaemorrhage	0 (0.0)	3 (0.4)
Cerebellar infarction	1 (0.2)	2 (0.3)
Cerebral haemorrhage	1 (0.2)	2 (0.3)
Cerebral haemosiderin deposition	0 (0.0)	2 (0.3)
Cerebral infarction	0 (0.0)	2 (0.3)
Presyncope	3 (0.7)	1 (0.1)
Ischaemic stroke	2 (0.4)	1 (0.1)
Balance disorder	0 (0.0)	1 (0.1)
Cerebrovascular accident	0 (0.0)	1 (0.1)
Cervicobrachial syndrome	0 (0.0)	1 (0.1)
Complex partial seizures	0 (0.0)	1 (0.1)
Depressed level of consciousness	0 (0.0)	1 (0.1)
Encephalopathy	0 (0.0)	1 (0.1)
Mental impairment	0 (0.0)	1 (0.1)
Post concussion syndrome	0 (0.0)	1 (0.1)
Subarachnoid haemorrhage	0 (0.0)	1 (0.1)
Akathisia	1 (0.2)	0 (0.0)
Dementia	1 (0.2)	0 (0.0)
Dementia of the Alzheimer's type, with delusions	1 (0.2)	0 (0.0)
Ischaemic cerebral infarction	1 (0.2)	0 (0.0)
Partial seizures with secondary generalisation	1 (0.2)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	11 (2.5)	27 (4.0)
Basal cell carcinoma	2 (0.4)	5 (0.7)
Breast cancer	1 (0.2)	4 (0.6)
Metastases to liver	0 (0.0)	2 (0.3)
Pancreatic carcinoma metastatic	0 (0.0)	2 (0.3)
Squamous cell carcinoma	2 (0.4)	1 (0.1)
Lung neoplasm malignant	1 (0.2)	1 (0.1)
Prostate cancer	1 (0.2)	1 (0.1)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Colon adenoma	0 (0.0)	1 (0.1)
Colon cancer	0 (0.0)	1 (0.1)
Glioma	0 (0.0)	1 (0.1)
Malignant melanoma in situ	0 (0.0)	1 (0.1)
Metastases to abdominal cavity	0 (0.0)	1 (0.1)
Myelodysplastic syndrome	0 (0.0)	1 (0.1)
Oesophageal cancer metastatic	0 (0.0)	1 (0.1)
Ovarian cancer	0 (0.0)	1 (0.1)
Ovarian epithelial cancer	0 (0.0)	1 (0.1)
Pancreatic carcinoma	0 (0.0)	1 (0.1)
Renal cancer metastatic	0 (0.0)	1 (0.1)
Signet-ring cell carcinoma	0 (0.0)	1 (0.1)
Squamous cell carcinoma of skin	0 (0.0)	1 (0.1)
Bladder transitional cell carcinoma	2 (0.4)	0 (0.0)
Chronic lymphocytic leukaemia	1 (0.2)	0 (0.0)
Malignant melanoma	1 (0.2)	0 (0.0)
Transitional cell carcinoma	1 (0.2)	0 (0.0)
Injury, poisoning and procedural complications	16 (3.6)	23 (3.4)
Hip fracture	3 (0.7)	3 (0.4)
Subdural haematoma	3 (0.7)	3 (0.4)
Fall	1 (0.2)	3 (0.4)
Femur fracture	1 (0.2)	2 (0.3)
Vascular pseudoaneurysm	0 (0.0)	2 (0.3)
Rib fracture	1 (0.2)	1 (0.1)
Subdural haemorrhage	1 (0.2)	1 (0.1)
Ankle fracture	0 (0.0)	1 (0.1)
Comminuted fracture	0 (0.0)	1 (0.1)
Face injury	0 (0.0)	1 (0.1)
Haematuria traumatic	0 (0.0)	1 (0.1)
Humerus fracture	0 (0.0)	1 (0.1)
Incorrect dose administered	0 (0.0)	1 (0.1)
Intentional overdose	0 (0.0)	1 (0.1)
Multiple injuries	0 (0.0)	1 (0.1)
Patella fracture	0 (0.0)	1 (0.1)
Pneumothorax traumatic	0 (0.0)	1 (0.1)
Road traffic accident	0 (0.0)	1 (0.1)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Spinal compression fracture	0 (0.0)	1 (0.1)
Pubis fracture	2 (0.4)	0 (0.0)
Accidental overdose	1 (0.2)	0 (0.0)
Clavicle fracture	1 (0.2)	0 (0.0)
Femoral neck fracture	1 (0.2)	0 (0.0)
Joint injury	1 (0.2)	0 (0.0)
Laceration	1 (0.2)	0 (0.0)
Limb traumatic amputation	1 (0.2)	0 (0.0)
Meningitis chemical	1 (0.2)	0 (0.0)
Postoperative ileus	1 (0.2)	0 (0.0)
Urinary retention postoperative	1 (0.2)	0 (0.0)
Wrist fracture	1 (0.2)	0 (0.0)
Psychiatric disorders	14 (3.1)	23 (3.4)
Behavioural and psychiatric symptoms of dementia	4 (0.9)	4 (0.6)
Agitation	3 (0.7)	4 (0.6)
Aggression	2 (0.4)	4 (0.6)
Mental status changes	1 (0.2)	4 (0.6)
Confusional state	2 (0.4)	2 (0.3)
Delirium	1 (0.2)	1 (0.1)
Abnormal behaviour	0 (0.0)	1 (0.1)
Anxiety	0 (0.0)	1 (0.1)
Hallucination, visual	0 (0.0)	1 (0.1)
Major depression	0 (0.0)	1 (0.1)
Mood disorder due to a general medical condition	0 (0.0)	1 (0.1)
Psychotic disorder	0 (0.0)	1 (0.1)
Suicide attempt	0 (0.0)	1 (0.1)
Depression	1 (0.2)	0 (0.0)
Suicidal ideation	1 (0.2)	0 (0.0)
Cardiac disorders	7 (1.6)	23 (3.4)
Bradycardia	1 (0.2)	3 (0.4)
Cardiac failure congestive	1 (0.2)	3 (0.4)
Myocardial infarction	1 (0.2)	3 (0.4)
Angina pectoris	0 (0.0)	3 (0.4)
Atrial fibrillation	2 (0.4)	2 (0.3)
Atrial flutter	1 (0.2)	2 (0.3)
Coronary artery disease	1 (0.2)	2 (0.3)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Sick sinus syndrome	0 (0.0)	2 (0.3)
Acute myocardial infarction	1 (0.2)	1 (0.1)
Atrioventricular block complete	0 (0.0)	1 (0.1)
Cardiac amyloidosis	0 (0.0)	1 (0.1)
Supraventricular tachycardia	0 (0.0)	1 (0.1)
Tachycardia	1 (0.2)	0 (0.0)
Infections and infestations	11 (2.5)	17 (2.5)
Urinary tract infection	4 (0.9)	5 (0.7)
Pneumonia	3 (0.7)	4 (0.6)
Appendicitis perforated	0 (0.0)	2 (0.3)
Bacteraemia	1 (0.2)	1 (0.1)
Abdominal abscess	0 (0.0)	1 (0.1)
Appendicitis	0 (0.0)	1 (0.1)
Arthritis infective	0 (0.0)	1 (0.1)
Gastroenteritis viral	0 (0.0)	1 (0.1)
Pelvic abscess	0 (0.0)	1 (0.1)
Soft tissue infection	0 (0.0)	1 (0.1)
Tracheobronchitis	0 (0.0)	1 (0.1)
Anal abscess	1 (0.2)	0 (0.0)
Bronchitis	1 (0.2)	0 (0.0)
Cellulitis	1 (0.2)	0 (0.0)
Cystitis	1 (0.2)	0 (0.0)
Influenza	1 (0.2)	0 (0.0)
Meningitis aseptic	1 (0.2)	0 (0.0)
Pyelonephritis	1 (0.2)	0 (0.0)
Septic shock	1 (0.2)	0 (0.0)
Urosepsis	1 (0.2)	0 (0.0)
Gastrointestinal disorders	9 (2.0)	14 (2.1)
Vomiting	3 (0.7)	2 (0.3)
Rectal prolapse	0 (0.0)	2 (0.3)
Gastrointestinal haemorrhage	1 (0.2)	1 (0.1)
Intestinal obstruction	1 (0.2)	1 (0.1)
Abdominal pain	0 (0.0)	1 (0.1)
Abdominal pain lower	0 (0.0)	1 (0.1)
Ascites	0 (0.0)	1 (0.1)
Coeliac artery stenosis	0 (0.0)	1 (0.1)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Diarrhoea	0 (0.0)	1 (0.1)
Duodenal ulcer	0 (0.0)	1 (0.1)
Dyspepsia	0 (0.0)	1 (0.1)
Gastric ulcer	0 (0.0)	1 (0.1)
Pancreatitis	0 (0.0)	1 (0.1)
Pancreatitis acute	0 (0.0)	1 (0.1)
Peptic ulcer	0 (0.0)	1 (0.1)
Small intestinal obstruction	0 (0.0)	1 (0.1)
Upper gastrointestinal haemorrhage	0 (0.0)	1 (0.1)
Constipation	1 (0.2)	0 (0.0)
Faecaloma	1 (0.2)	0 (0.0)
Gastrooesophageal reflux disease	1 (0.2)	0 (0.0)
Haematochezia	1 (0.2)	0 (0.0)
Nausea	1 (0.2)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	6 (1.3)	11 (1.6)
Chronic obstructive pulmonary disease	1 (0.2)	3 (0.4)
Pleural effusion	0 (0.0)	3 (0.4)
Pulmonary embolism	1 (0.2)	2 (0.3)
Asthma	0 (0.0)	2 (0.3)
Acute respiratory failure	0 (0.0)	1 (0.1)
Dyspnoea	0 (0.0)	1 (0.1)
Pneumothorax	0 (0.0)	1 (0.1)
Eosinophilic pneumonia	1 (0.2)	0 (0.0)
Laryngospasm	1 (0.2)	0 (0.0)
Lung infiltration	1 (0.2)	0 (0.0)
Respiratory arrest	1 (0.2)	0 (0.0)
Metabolism and nutrition disorders	3 (0.7)	10 (1.5)
Dehydration	2 (0.4)	8 (1.2)
Diabetic foot	0 (0.0)	1 (0.1)
Diabetic ketoacidosis	0 (0.0)	1 (0.1)
Decreased appetite	1 (0.2)	0 (0.0)
Hypophagia	1 (0.2)	0 (0.0)
Musculoskeletal and connective tissue disorders	3 (0.7)	10 (1.5)
Back pain	0 (0.0)	2 (0.3)
Costochondritis	0 (0.0)	2 (0.3)
Muscular weakness	1 (0.2)	1 (0.1)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Musculoskeletal chest pain	0 (0.0)	1 (0.1)
Musculoskeletal pain	0 (0.0)	1 (0.1)
Neck pain	0 (0.0)	1 (0.1)
Osteonecrosis	0 (0.0)	1 (0.1)
Sensation of heaviness	0 (0.0)	1 (0.1)
Osteoarthritis	1 (0.2)	0 (0.0)
Pain in extremity	1 (0.2)	0 (0.0)
Hepatobiliary disorders	2 (0.4)	9 (1.3)
Cholelithiasis	1 (0.2)	5 (0.7)
Cholecystitis	0 (0.0)	3 (0.4)
Cholecystitis acute	0 (0.0)	2 (0.3)
Bile duct stone	0 (0.0)	1 (0.1)
Gallbladder pain	1 (0.2)	0 (0.0)
Vascular disorders	6 (1.3)	8 (1.2)
Deep vein thrombosis	2 (0.4)	3 (0.4)
Hypotension	1 (0.2)	3 (0.4)
Orthostatic hypotension	2 (0.4)	1 (0.1)
Arterial haemorrhage	0 (0.0)	1 (0.1)
Accelerated hypertension	1 (0.2)	0 (0.0)
Hypertension	1 (0.2)	0 (0.0)
Renal and urinary disorders	4 (0.9)	7 (1.0)
Renal failure acute	2 (0.4)	2 (0.3)
Nephrolithiasis	1 (0.2)	2 (0.3)
Calculus bladder	0 (0.0)	1 (0.1)
Calculus ureteric	0 (0.0)	1 (0.1)
Neurogenic bladder	0 (0.0)	1 (0.1)
Renal failure	0 (0.0)	1 (0.1)
Hydronephrosis	1 (0.2)	0 (0.0)
Urinary retention	1 (0.2)	0 (0.0)
General disorders and administration site conditions	6 (1.3)	6 (0.9)
Chest pain	2 (0.4)	2 (0.3)
Asthenia	0 (0.0)	2 (0.3)
Pyrexia	1 (0.2)	1 (0.1)
Gait disturbance	0 (0.0)	1 (0.1)
Non-cardiac chest pain	2 (0.4)	0 (0.0)
Device failure	1 (0.2)	0 (0.0)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Investigations	3 (0.7)	2 (0.3)
Electrocardiogram QT prolonged	0 (0.0)	1 (0.1)
Liver function test abnormal	0 (0.0)	1 (0.1)
Blood pressure decreased	1 (0.2)	0 (0.0)
Blood pressure increased	1 (0.2)	0 (0.0)
Vitamin B12 decreased	1 (0.2)	0 (0.0)
Reproductive system and breast disorders	1 (0.2)	2 (0.3)
Benign prostatic hyperplasia	0 (0.0)	1 (0.1)
Ovarian cyst	0 (0.0)	1 (0.1)
Uterine prolapse	1 (0.2)	0 (0.0)
Blood and lymphatic system disorders	0 (0.0)	2 (0.3)
Anaemia	0 (0.0)	2 (0.3)
Ear and labyrinth disorders	0 (0.0)	1 (0.1)
Vertigo positional	0 (0.0)	1 (0.1)
Immune system disorders	0 (0.0)	1 (0.1)
Hypersensitivity	0 (0.0)	1 (0.1)
Congenital, familial and genetic disorders	1 (0.2)	0 (0.0)
Atrial septal defect	1 (0.2)	0 (0.0)
Eye disorders	1 (0.2)	0 (0.0)
Diplopia	1 (0.2)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (0.2)	0 (0.0)
Eczema	1 (0.2)	0 (0.0)

b. *APOE*ε4 Non-Carrier Study (Safety Population)*

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=524) n (%)	Bapineuzumab		
		0.5 mg/kg (N=337) n (%)	1.0 mg/kg (N=329) n (%)	2.0 mg/kg (N=141) n (%)
Number of Subjects With Any Serious TEAE	108 (20.6)	72 (21.4)	76 (23.1)	38 (27.0)
Nervous system disorders	21 (4.0)	22 (6.5)	23 (7.0)	14 (9.9)
Vasogenic cerebral oedema	0 (0.0)	5 (1.5)	5 (1.5)	7 (5.0)
Syncope	5 (1.0)	4 (1.2)	4 (1.2)	4 (2.8)
Convulsion	4 (0.8)	1 (0.3)	6 (1.8)	2 (1.4)
Cerebral infarction	0 (0.0)	1 (0.3)	3 (0.9)	0 (0.0)
Dizziness	1 (0.2)	0 (0.0)	2 (0.6)	0 (0.0)
Presyncope	1 (0.2)	0 (0.0)	2 (0.6)	0 (0.0)
Encephalopathy	1 (0.2)	1 (0.3)	1 (0.3)	0 (0.0)
Cerebral haemorrhage	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)
Cerebral microhaemorrhage	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)
Cerebrovascular accident	1 (0.2)	2 (0.6)	0 (0.0)	0 (0.0)
Thalamic infarction	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.7)
Dementia	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Dysarthria	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Haemorrhagic stroke	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Altered state of consciousness	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Cerebral haemosiderin deposition	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Dementia of the Alzheimer's type, with delusions	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Hemiparesis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Motor neurone disease	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Radiculopathy	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Somnolence	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Subdural hygroma	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Dementia Alzheimer's type	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Grand mal convulsion	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Cerebellar infarction	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Cerebral ischaemia	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Encephalitis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Intraventricular haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Subarachnoid haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Lacunar infarction	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Transient ischaemic attack	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Brain stem infarction	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Carotid artery stenosis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cerebrovascular disorder	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cognitive disorder	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Metabolic encephalopathy	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Myoclonus	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Partial seizures	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
VIIth nerve paralysis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Infections and infestations	19 (3.6)	10 (3.0)	17 (5.2)	5 (3.5)
Pneumonia	8 (1.5)	3 (0.9)	8 (2.4)	1 (0.7)
Diverticulitis	1 (0.2)	0 (0.0)	4 (1.2)	1 (0.7)
Cellulitis	0 (0.0)	1 (0.3)	2 (0.6)	1 (0.7)
Urinary tract infection	6 (1.1)	0 (0.0)	2 (0.6)	1 (0.7)
Sepsis	1 (0.2)	0 (0.0)	2 (0.6)	0 (0.0)
Abscess intestinal	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Clostridium difficile colitis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Enterobacter sepsis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Herpes zoster	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Soft tissue infection	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Urosepsis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Gastroenteritis	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Extradural abscess	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Gastritis viral	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Pneumonia mycoplasmal	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Staphylococcal infection	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Upper respiratory tract infection	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Bronchitis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Gastroenteritis viral	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Urinary tract infection bacterial	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	17 (3.2)	9 (2.7)	12 (3.6)	3 (2.1)
Hip fracture	2 (0.4)	4 (1.2)	4 (1.2)	0 (0.0)
Spinal compression fracture	0 (0.0)	2 (0.6)	2 (0.6)	0 (0.0)
Subdural haematoma	6 (1.1)	0 (0.0)	2 (0.6)	1 (0.7)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Cervical vertebral fracture	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Femur fracture	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Head injury	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Open fracture	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Road traffic accident	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Fall	5 (1.0)	1 (0.3)	0 (0.0)	0 (0.0)
Confusion postoperative	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Femoral neck fracture	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Fibula fracture	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Spinal fracture	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Comminuted fracture	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Pubis fracture	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Facial bones fracture	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Jaw fracture	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Lower limb fracture	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Near drowning	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skull fractured base	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Thoracic vertebral fracture	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Gastrointestinal disorders	3 (0.6)	6 (1.8)	11 (3.3)	2 (1.4)
Gastritis	0 (0.0)	1 (0.3)	2 (0.6)	1 (0.7)
Gastrointestinal haemorrhage	0 (0.0)	1 (0.3)	1 (0.3)	0 (0.0)
Abdominal pain	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Small intestinal obstruction	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Abdominal pain lower	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Colitis ischaemic	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Constipation	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Diarrhoea	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Diverticulitis intestinal haemorrhagic	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Rectal perforation	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Volvulus	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Vomiting	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Abdominal pain upper	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Colitis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Gastritis erosive	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Proctitis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Rectal ulcer	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Faecaloma	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Rectal prolapse	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac disorders	19 (3.6)	8 (2.4)	9 (2.7)	9 (6.4)
Atrial fibrillation	6 (1.1)	2 (0.6)	2 (0.6)	1 (0.7)
Myocardial infarction	1 (0.2)	1 (0.3)	2 (0.6)	1 (0.7)
Coronary artery disease	1 (0.2)	2 (0.6)	1 (0.3)	0 (0.0)
Acute myocardial infarction	1 (0.2)	0 (0.0)	2 (0.6)	1 (0.7)
Angina pectoris	0 (0.0)	1 (0.3)	1 (0.3)	3 (2.1)
Bradycardia	1 (0.2)	0 (0.0)	1 (0.3)	1 (0.7)
Atrioventricular block first degree	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Cardiovascular disorder	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Hypertensive heart disease	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Cardiac failure congestive	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Sinus bradycardia	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Sick sinus syndrome	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.7)
Cardiac arrest	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Cardio-respiratory arrest	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Pericardial haemorrhage	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Ventricular tachycardia	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Acute coronary syndrome	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Aortic valve incompetence	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Atrial flutter	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Atrial tachycardia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Atrioventricular block	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cardiac tamponade	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Coronary artery occlusion	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pericardial effusion	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Sinus arrest	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	24 (4.6)	10 (3.0)	6 (1.8)	7 (5.0)
Squamous cell carcinoma	2 (0.4)	2 (0.6)	3 (0.9)	1 (0.7)
Prostate cancer	4 (0.8)	3 (0.9)	0 (0.0)	0 (0.0)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Malignant melanoma	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Brain neoplasm	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Non-small cell lung cancer	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Basal cell carcinoma	4 (0.8)	1 (0.3)	0 (0.0)	1 (0.7)
Breast cancer	4 (0.8)	1 (0.3)	0 (0.0)	0 (0.0)
Colon cancer metastatic	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Gallbladder cancer	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Kaposi's sarcoma	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Metastases to liver	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Prostate cancer metastatic	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Squamous cell carcinoma of skin	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Basosquamous carcinoma of skin	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Bladder neoplasm	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Lipoma	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Lung neoplasm malignant	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Mesothelioma	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Colon cancer	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Endometrial cancer	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Essential thrombocythaemia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Large granular lymphocytosis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Laryngeal cancer	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Non-small cell lung cancer stage IV	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skin cancer	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Spindle cell sarcoma	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Vascular disorders	10 (1.9)	4 (1.2)	5 (1.5)	1 (0.7)
Deep vein thrombosis	5 (1.0)	2 (0.6)	1 (0.3)	0 (0.0)
Aortic aneurysm	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Arteriosclerosis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Haematoma	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Jugular vein thrombosis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Hypertension	2 (0.4)	1 (0.3)	0 (0.0)	0 (0.0)
Orthostatic hypotension	2 (0.4)	1 (0.3)	0 (0.0)	0 (0.0)
Thrombosis	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Accelerated hypertension	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab			
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)	
Psychiatric disorders			0.5 mg/kg	1.0 mg/kg	2.0 mg/kg
Delirium	10 (1.9)	5 (1.5)	4 (1.2)	5 (3.5)	
Confusional state	0 (0.0)	1 (0.3)	2 (0.6)	0 (0.0)	
Mental status changes	0 (0.0)	1 (0.3)	1 (0.3)	1 (0.7)	
Depression	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)	
Anxiety disorder due to a general medical condition	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	
Agitation	3 (0.6)	1 (0.3)	0 (0.0)	2 (1.4)	
Suicide attempt	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	
Psychotic disorder	3 (0.6)	0 (0.0)	0 (0.0)	1 (0.7)	
Aggression	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.7)	
Polydipsia psychogenic	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	
Abnormal behaviour	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Emotional disorder	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Major depression	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Paranoia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Personality disorder	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Metabolism and nutrition disorders			5 (1.0)	3 (0.9)	3 (0.9)
Dehydration	3 (0.6)	2 (0.6)	0 (0.0)	0 (0.0)	
Hypoglycaemia	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.7)	
Hyperkalaemia	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	
Hypophagia	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	
Hypokalaemia	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)	
Hypovolaemia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Renal and urinary disorders			6 (1.1)	0 (0.0)	5 (1.5)
Renal failure acute	3 (0.6)	0 (0.0)	2 (0.6)	0 (0.0)	
Nephrolithiasis	0 (0.0)	0 (0.0)	2 (0.6)	0 (0.0)	
Haematuria	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)	
Urinary retention	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)	
Azotaemia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Calculus ureteric	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Renal failure	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	
Respiratory, thoracic and mediastinal disorders			6 (1.1)	2 (0.6)	3 (0.9)
Chronic obstructive pulmonary disease	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)	

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Pulmonary embolism	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Emphysema	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Respiratory distress	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Pneumothorax	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Pulmonary fibrosis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Lung infiltration	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonia aspiration	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pneumonitis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Stridor	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatobiliary disorders	3 (0.6)	5 (1.5)	0 (0.0)	0 (0.0)
Cholecystitis	0 (0.0)	3 (0.9)	0 (0.0)	0 (0.0)
Cholecystitis acute	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Cholangitis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Cholangitis acute	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Cholelithiasis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Hepatitis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Musculoskeletal and connective tissue disorders	5 (1.0)	2 (0.6)	2 (0.6)	2 (1.4)
Back pain	0 (0.0)	1 (0.3)	1 (0.3)	1 (0.7)
Osteoarthritis	2 (0.4)	1 (0.3)	1 (0.3)	0 (0.0)
Musculoskeletal chest pain	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Rhabdomyolysis	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Lumbar spinal stenosis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pain in extremity	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pathological fracture	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Skin and subcutaneous tissue disorders	1 (0.2)	2 (0.6)	2 (0.6)	0 (0.0)
Decubitus ulcer	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Hyperhidrosis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Actinic keratosis	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Angioedema	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
General disorders and administration site conditions	5 (1.0)	1 (0.3)	1 (0.3)	1 (0.7)
Oedema peripheral	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Chest pain	1 (0.2)	1 (0.3)	0 (0.0)	0 (0.0)
Multi-organ failure	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)

Treatment-Emergent Serious Adverse Events by System Organ Class and Preferred Term (Safety Analysis Population) (Non-carrier Study)

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	(N=524) n (%)	(N=337) n (%)	(N=329) n (%)	(N=141) n (%)
Asthenia	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)
Death	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Pyrexia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Immune system disorders	0 (0.0)	2 (0.6)	0 (0.0)	0 (0.0)
Anaphylactic reaction	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Hypersensitivity	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Eye disorders	2 (0.4)	0 (0.0)	1 (0.3)	0 (0.0)
Diplopia	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Retinal vein thrombosis	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Ear and labyrinth disorders	1 (0.2)	0 (0.0)	1 (0.3)	0 (0.0)
Vertigo	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Meniere's disease	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Investigations	0 (0.0)	1 (0.3)	0 (0.0)	1 (0.7)
Liver function test abnormal	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Cardiac murmur	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Blood and lymphatic system disorders	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Anaemia	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)

Table S7. Treatment-Emergent Adverse Events That Led to Death by System Organ Class

a. *APOE*ε4* Carrier Study (Safety Population)

Treatment-Emergent Adverse Events That Led to Death by System Organ Class and Preferred Term (Safety Analysis Population) (Carrier Study)

Body System Or Organ Class Preferred Term	Placebo (N=448) n (%)	Bapineuzumab 0.5 mg/kg (N=673) n (%)
Number of Subjects With Any TEAE Leading to Death	5 (1.1)	15 (2.2)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0.0)	6 (0.9)
Metastases to abdominal cavity	0 (0.0)	1 (0.1)
Metastases to liver	0 (0.0)	1 (0.1)
Oesophageal cancer metastatic	0 (0.0)	1 (0.1)
Ovarian cancer	0 (0.0)	1 (0.1)
Ovarian epithelial cancer	0 (0.0)	1 (0.1)
Pancreatic carcinoma	0 (0.0)	1 (0.1)
Renal cancer metastatic	0 (0.0)	1 (0.1)
Nervous system disorders	3 (0.7)	3 (0.4)
Dementia Alzheimer's type	2 (0.4)	3 (0.4)
Dementia	1 (0.2)	0 (0.0)
Cardiac disorders	1 (0.2)	3 (0.4)
Cardiac failure congestive	0 (0.0)	2 (0.3)
Myocardial infarction	1 (0.2)	1 (0.1)
General disorders and administration site conditions	0 (0.0)	1 (0.1)
Asthenia	0 (0.0)	1 (0.1)
Infections and infestations	0 (0.0)	1 (0.1)
Pneumonia	0 (0.0)	1 (0.1)
Injury, poisoning and procedural complications	0 (0.0)	1 (0.1)
Multiple injuries	0 (0.0)	1 (0.1)
Metabolism and nutrition disorders	0 (0.0)	1 (0.1)
Diabetic ketoacidosis	0 (0.0)	1 (0.1)
Respiratory, thoracic and mediastinal disorders	1 (0.2)	0 (0.0)
Respiratory arrest	1 (0.2)	0 (0.0)

b. *APOE*ε4* Non-Carrier Study (Safety Population)

**Treatment-Emergent Adverse Events That Led to Death by System Organ Class and Preferred Term
(Safety Analysis Population) (Non-Carrier Study)**

Body System Or Organ Class Preferred Term	Placebo	Bapineuzumab		
	0.5 mg/kg (N=524) n (%)	1.0 mg/kg (N=337) n (%)	2.0 mg/kg (N=329) n (%)	2.0 mg/kg (N=141) n (%)
Number of Subjects With Any TEAE Leading to Death	7 (1.3)	4 (1.2)	7 (2.1)	5 (3.5)
Cardiac disorders	0 (0.0)	0 (0.0)	3 (0.9)	3 (2.1)
Myocardial infarction	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.7)
Cardiovascular disorder	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Coronary artery disease	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Cardiac arrest	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Cardio-respiratory arrest	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Nervous system disorders	2 (0.4)	3 (0.9)	0 (0.0)	1 (0.7)
Cerebral haemorrhage	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Encephalopathy	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Motor neurone disease	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Dementia Alzheimer's type	1 (0.2)	0 (0.0)	0 (0.0)	1 (0.7)
Cognitive disorder	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Infections and infestations	0 (0.0)	0 (0.0)	2 (0.6)	0 (0.0)
Pneumonia	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Sepsis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2 (0.4)	0 (0.0)	1 (0.3)	2 (1.4)
Non-small cell lung cancer	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Lung neoplasm malignant	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Mesothelioma	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Laryngeal cancer	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Non-small cell lung cancer stage IV	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Renal and urinary disorders	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Renal failure acute	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Vascular disorders	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Arteriosclerosis	0 (0.0)	0 (0.0)	1 (0.3)	0 (0.0)
Respiratory, thoracic and mediastinal disorders	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Pulmonary fibrosis	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
General disorders and administration site conditions	2 (0.4)	0 (0.0)	0 (0.0)	1 (0.7)
Multi-organ failure	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.7)
Asthenia	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Death	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Injury, poisoning and procedural complications	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)
Subdural haematoma	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)